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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,305	03/22/1999	NICHOLAS MANOLIOS	06025.0003	2721
22428	7590	10/15/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,305

Applicant(s)

NICHOLAS MANOLIOS

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-4, 6 and 13 is/are rejected.
- 7) ☒ Claim(s) 5-8 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed, 8-4-04, is acknowledged. Claim 1 was amended. Claims 1, 3-14 are pending in this application.

Election/Restrictions

2. Applicant's election with traverse of Group I and the species of SEQ ID. No. 7 in Paper No. 7 and 13 is acknowledged. Claims 1, 3-14 correspond to Group I.

Thus, as indicated in the previous office action, allowability was established for the species corresponding to SEQ ID NO: 6-15 and 17-26. Applicants have amended the claims and as such, the search was extended in the Markush group and a peptide was found that read on generic claim

Although claims 9-11 and 14 were examined with respect to SEQ ID. No 6-15 and 17-26 , the are none the less held as non-elected claims since they did not read on the elected species found in the prior art.

Claims 1, 3-4 have been examined to the extent they read on the prior art. Claims drawn to the nonelected species, claims 10-11, 14 are held withdrawn from further consideration.

3. In light of the amendment, All rejections made in the previous office action are hereby withdrawn and New Grounds for Rejections follows below.

New Grounds For Rejection

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-4, 6 and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Grey et al.

Claims drawn to the nonelected species, claims 9, 10-11, 14-15 are held withdrawn from further consideration.

The reference teaches HLA-A2.1 peptides that are useful in eliciting an immune response against a desired antigen (see abstract). The reference discloses peptide NH₂-Leu-Leu-Lue-Cys-Arg-Leu-Pro-Phe-Leu-COOH₂ (LLCRLPFL) and NH₂-Leu-Lue-Lue-Tyr-Tyr-Asp-Tyr-Ser-Leu-COOH (LLYYDYSL) as the peptides that is effective to treat immunoinflammatory conditions (see table 22 on page 70). The reference discloses numerous pharmaceutical formulations of the peptides for treating viral infections (see page 21-22). This teaching meets the limitation of claim 13. The peptide read on the claimed invention because R1 is allowed to be NH₂, the first X variable is allowed to be LLC in the first peptide and LLYY in the second peptide, Z is Arg or Asp, the second X is LPFL or YSL, and R2 is COOH. Note that Ile, Leu, Val, Pro are all conventionally known in the art to be a hydrophobic amino acid that is neutral. By virtue of having these amino acids residues, the reference meets the limitation of claim 3. The presence of Arg and Asp meet the limitation of claim 6.

Finally, although the reference does not teach that the peptides inhibit T-cell antigen receptor, such claimed language of is an intended use limitation and intended use or field of use. However, intended use limitation and intended use or field of use for the invention generally will

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not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*. Here the reference disclose a peptide that meets all of the structural limitations, and accordingly claimed limitations are met.

Therefore, the reference anticipates the claimed invention.

5. Claims 5-8 and 12 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

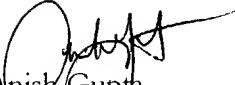
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta
Patent Examiner



BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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